Use of ACGIH TLV-TWAs to Predict Ambient Air Standards Based on IRIS IRfCs and IURs

Steven F. Cross

Environmental Planner, Washington Dept. of Ecology Air Quality Program, POB 47600, Olympia, WA 98504, 360-407-6875, <u>stcr461@ecy.wa.gov</u> 2004 September 30

Abstract

Ambient air standards are used by regulatory agencies to quantify protection of the general public from air emissions. TLVs are occupational exposure values, while EPA's IRIS IUR and IRfC values relate to the general public. In the absence of IRIS values, many agencies use TLVs as a source for deriving ambient air standards by subjecting each TLV to a reduction factor. The method used by Washington is explained. Some other methods in current use are discussed. TLVs are used in this paper to predict ambient air standards based on IRIS IRfCs and IURs with the formula <u>0.000019×TLV^{1.31}</u>.

Keywords

air quality, ambient air standard, environmental toxicology, ACGIH, TLV, IRIS, IRfC, IUR

Problem

To decide whether proposed projects should be permitted, regulatory agencies need objective standards that can be routinely derived and kept up to date, sometimes without ongoing toxicological expertise. There is a widespread preference for using IRIS values for generating such standards. There being many more substances with TLVs than with IRIS values however, many regulatory agencies use those occupational air quality standards to derive ambient air quality standards for the general population by simply dividing them by a reduction factor. The Brief & Scala model suggested in the ACGIH booklet coincides with this approach. However, the widespread regulatory preference for IRIS derived ambient standards suggests that TLV-based ambient standards should be normalized to IRIS values. Is there another simple, replicable, objective formula that is better than the reduction factor approach?

Acronyms & Abbreviations

ACGIH American Conference of Governmental Health Officials

ASIL Ambient Source Impact Level, WAC 173-460-020(2)

EPA United States Environmental Protection Agency

IRfC Inhalation Reference Concentration

IRIS Integrated Risk Information System, http://www.epa.gov/iris/

IUR Inhalation Unit Risk

NSR New Source Review

TAP Toxic Air Pollutant, WAC 173-460-020(20)

TLV ACGIH Threshold Limit Value TWA

TWA Time Weighted Average

Washington NSR Regulatory Information

There are rules in the state of Washington requiring new sources of air pollution to obtain permits; sections of Chapter 173-400 WAC for criteria air pollutants, and Chapter 173-460 WAC for TAPs. Washington regulates 674 chemical substances it calls TAPs. Washington established ambient screening standards called ASILs in 1990 and 1994. ASILs are protective screening concentrations for TAPs. A concentration less than an ASIL is presumptively safe or presents acceptable risk. Whether a concentration greater than an ASIL is safe or acceptable may be determined by further risk assessment.

The ASILs were derived by a formulaic approach. The sources for the derivation were as follows; 55 from IRIS, 481 from ACGIH, 3 from other sources, 42 from unknown sources, and 93 are without ASILs. This formulaic approach was meant to be straight forward, replicable, and objective.

EPA's IRIS is the preferred source of data for deriving an ASIL. An IRIS IUR is the upper-bound risk associated with lifetime exposure to 1 $\mu g/m^3$ of a substance. The ASIL is the concentration ($\mu g/m^3$) of the TAP corresponding to a risk of 1:1,000,000. The ASIL equals one one-millionth divided by the IUR. (0.000001/IUR) An IRIS IRfC is the concentration of a substance to which a person could be exposed for a lifetime without expecting adverse health effects, allowing for uncertainty and sensitive subgroups. The ASIL equals the IRfC, although different units are used. The ASIL ($\mu g/m^3$) equals the IRfC ($m g/m^3$) multiplied by 1000 ($\mu g/mg$). (IRfC × 1000) Inhalation IURs are exclusively used, not ingestion IURs.

If an IRIS IRfC or IUR is not available, the ASIL may be derived from a TLV using a reduction factor approach. TLVs are occupational standards based on an 8-hour day and a 5-day week. The ASIL equals the TLV divided by 3 to convert from an 8-hour to a 24-hour per day 5-day workweek, further divided by 10 to account for a healthy worker population vis-à-vis sensitive members of the general population, further divided by 10 to reflect that there is no recovery period for continuous residential exposure, and multiplied by 1000 to convert mg to μ g. In short, the ASIL (μ g/m³) equals the TLV (μ g/m³) multiplied by 1000/300. (TLV × 10/3)

Other States' Use of Reduction Factors

Several other states apply a reduction factor to TLVs to derive ambient air standards. The reduction factors account for several factors, including; 1) TLVs are premised on an 8-hour work-day and 5-day workweek, while ambient standards are premised on continuous exposure for a lifetime, 2) TLVs are premised on a worker population that is relatively more healthy than the general population, and 3) generic application of "safety factors." Other states use factors ranging from 1/10 to 1/4200. See Table 1. While these various reduction factors were all concocted through a rational regulatory process, they are not mathematically linked to an objective scientific standard.

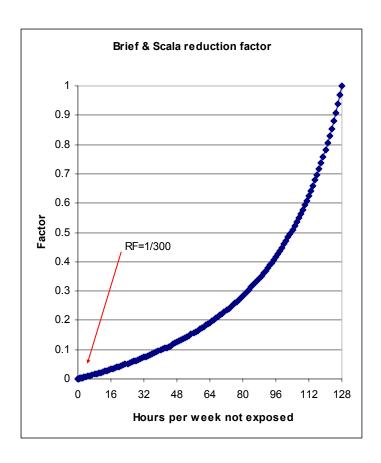
Table 1: Some States Using the TLV × RF Method						
State	Reduction Factor	Citation				
		R 336.1232(c)				
Michigan, ITSL	1/100	http://www.deq.state.mi.us/				
		AQD/rules/New%20Rules.htm				
New Hampshire, AAL		Env-A-1400				
(safety and time factors)	1/(24 to 420)	http://www.des.state.nh.us/				
(safety and time factors)		<u>rules/env-a1400.pdf</u>				
Vermont, HAAS	1/(42, 420, or 4200)	section 5-261, appendix D				
(accumulation and	or	http://www.anr.state.vt.us/				
uncertainty factors)	1/(10, 100, or 1000)	air/docs/apcregs.pdf				
		WAC 173-460				
Washington, ASIL	1/300	http://www.ecy.wa.gov/				
		biblio/wac173460.html				
Wisconsin, AAC		NR 445.04 & .05				
(1-hr or 24-hr)	1/(10 or 42)	http://www.dnr.state.wi.us/				
(1-111 01 24-111)		org/aw/air/reg/NR400toc.htm				

Brief & Scala Model

The TLV booklet, ACGIH, 2004, page 10, references another reduction factor method for extending application of TLVs beyond the 40-hr workweek. For exposures greater than the standard workweek, but less than continuous, the TLV booklet refers to the Brief and Scala model in Paustenbach, 2000. The model is based on the concept of steady state concentration in body burden resulting from biological half-life. The model uses the following equation to derive a reduction factor.

This equation results in a TLV reduction factor method for any given combination of hours. The reduction factor diminishes nonlinearly towards zero as the hours of nonexposure approach zero and the hours of exposure approach 168.

The Brief & Scala model can rationalize regulatory reduction factors. For example, Washington's reduction factor of 1/300 would result from 166.326 hrs/wk of exposure (less than 2 hrs/wk of non-exposure). Yet, this stretches applicability of the model, it falls short of Washington's duty to protect all citizens from continuous exposure, and it does not compare to the continuous exposure assumptions in IRIS.



Use of TLVs

The TLV values have been subject to critical review for various reasons. Castleman, 1988, found reliance on unpublished corporate communications, conflicts of interest and proindustry bias. Ziem, 1989, reviewed the history of the ACGIH from 1938 and described the medical inadequacy of the TLVs. Roach, 1990, pointed out that TLVs were poorly correlated with the incidence of adverse effects, that TLVs were well correlated with the exposure levels reported when the limits were adopted, and that interpretations of exposure-response relationships were inconsistent between the TLV committee and the authors of studies cited in the 1976 Documentation. Roach concluded that TLVs are a compromise between health-based considerations and practical industrial considerations, "with the balance seeming to strongly favor the latter."

The 2004 TLV booklet presents an updated statement by the ACGIH board cautioning against excessive reliance on TLVs. Yet, the existence of 640 numbers of widespread accessibility and understanding encourages their utilization. The advantage is their pervasiveness and breadth. The problem with using TLVs to derive ambient standards is adapting them to continuous exposure by a general population. This paper suggests a way to better use TLVs for substances where no IRIS value is available without fundamentally changing existing regulatory structures.

Predicting IRIS-based ASILs from TLV values

IRIS values are the preferred choice for establishing ambient standards in Washington, and generally elsewhere. Comparing IRIS and TLV values is not a unique idea, e.g., Alavanja, 1990, nor is using linear regression to derive useful numbers from existing numbers, e.g., Whaley, 2000. This paper derives estimated IRIS values from existing TLV numbers. While it is not an express goal of Washington's TLV derived ASILs to mimic IRIS derived ASILs, the worthiness of this goal is implied in the preference for IRIS. How do the hundreds of TLV derived ASILs look in lieu of IRIS values?

As of the spring of 2004, there are 56 IURs and 72 IRfCs, 12 of which are for the same substances. In addition to these 116 IRIS values that could be converted to ASILs there are 622 such TLVs. There are 76 substances for which both the ACGIH provides a TLV, and EPA provides an IUR or IRfC. These 76 substances can be subjected to analysis.

Table 3 is a list of the 76 substances for which both ACGIH provides a TLV and IRIS provides an IUR or IRfC. The numbers in the leftmost two columns are converted to uniform units for the analysis as follows. The IRIS value is the lesser of $0.000001/IUR \, \mu g/m^3$ or $1000 \, \mu g/mg \times IRfC \, mg/m^3$. The TLV values given in ppm were converted to mg/m^3 by the TLV booklet formula (TLVppm × molecular weight)/24.45. Values in mg/m^3 are multiplied by 1000 for conversion to units of $\mu g/m^3$. Values for asbestos were further converted from fibers/cm³ and fibers/ml to fibers/m³.

Whether to include asbestos may be debated on the grounds of its being measured in units of fibers instead of mg. Indeed, since asbestos does have an IRIS value, there is no need to derive a value from its TLV. On the other hand, the asbestos point is not an outlier on the graph in Figure 1. Regardless, the approach of this paper stands, and the resulting formula would be affected by an uninteresting amount.

Figure 1 is a scatter plot of the results, both axes being logarithmic. There is an obvious and unsurprising trend that x increases with y; *i.e.*, the more toxic ACGIH considers a substance, the more toxic EPA likewise considers it. The equation for the least squares regression line is $0.000019 \times \text{TLV}^{1.31}$ with an R² of 0.70. The R² may be deemed to show a good correlation considering the independent and subjective origin of the two sets of numbers.

Discussion of Results

The intercept of the regression line unsurprisingly shows that the ACGIH values are relatively high. This is what a reduction factor would seek to address. The slope is more intriguing. It shows that as the ACGIH numbers rise, the IRIS numbers rise more quickly. Relative to IRIS, ACGIH shows more conservatism towards less toxic substances than towards those more toxic. Likewise, IRIS expresses relatively lower limits on its more toxic substances. The slope quantifies this relative high-low bias between ACGIH and IRIS.

Further study of subsets of the 76 substances might elucidate this bias. For example, the plotted points in Figure 1 differentiate IUR-derived ASILs from IRfC-derived ASILs. The

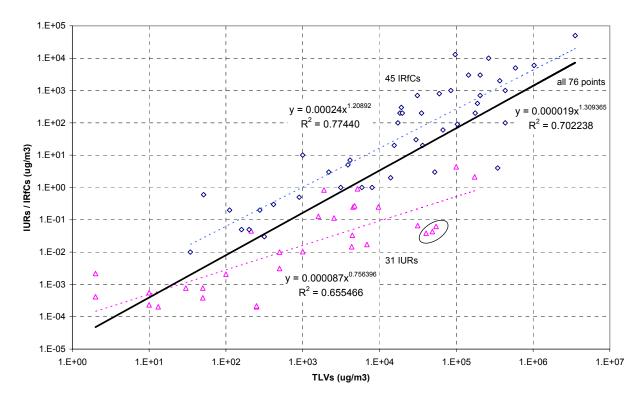


Figure 1: Compare TLVs to IURs / IRfCs

dotted lines are separate regression lines for these. Examination of the two subsets of points helps in understanding the overall shape of the plot. For example, the slope would be closer to 1 if the substances with IURs had lower TLVs or higher IURs, and the substances with IRfCs had higher TLVs or lower IRfCs.

The subplots on Figure 1 may seem to suggest using two separate regression equations instead of the one. This would require separating the TLV numbers into two subsets equivalent to the IRIS IURs and IRfC subsets. Whereas IRIS uses an A-D classification, ACGIH uses an A1-A5 system. There does not seem to be a useful correlation between the respective classifications, however. Subplots based on ACGIH classifications are not much different than the basic overall plot. The lower dotted line in Figure 1, the regression line for IRIS carcinogens, shows less correlation. This may suggest that, to better correlate with EPA, the ACGIH should focus efforts on refining the TLVs for carcinogens. Specifically, the three substances highlighted in Table 3 and circled on Figure 1 fall just outside the lower 95% prediction interval.

Figure 2 compares the status quo in Washington with the approach suggested by this paper. Compared to the predicted IRIS values, the reduction factor ASILs are shown to be too high by factors ranging from only 1.6 to as much as 139. While this difference may not be considered dramatic, it might be objectionable to the regulated community because it represents a tightening of standards. Yet, if IRIS predicted from TLV numbers are better than reduction factor numbers, then they should be used.

1.E+05 RF = reduction factor RF=1.6 1.E+04 1.E+03 RF=300 1.E+02 IURs / IRfCs (ug/m3) 1.E+01 TLV v. predicted IRIS 1.E+00 TLV / 300, i.e. Washington **ASIL** 1.E-01 regression line from Figure 1 1.E-02 1.E-03 RF=300 1.E-04 RF=139 1.E-05 1.E-05 1.E-04 1.E-03 1.E-02 1.E+01 1.E+02 1.E+03 1.E+04 1.E+05 TLVs, Reduced TLVs, and Predicted TLVs (ug/m3)

Figure 2: Compare 76 TLVs to IURs / IRfCs

The TLVs are updated through publication of the TLV booklet the early spring of each year, with just a couple percent of newly adopted values. The IRIS values are updated on an ongoing basis published on the internet, with just a few changes per year. Thus, there are unique combinations of TLVs, IURs, and IRfCs published as time progresses. The predictive formula concomitantly changes. Table 2 presents three such results over three years. The three year trend is consistent, but the change is just noticeable, and then so at the lowest values. The slope has steepened, away from 1, with the pivot point in the lower values. In Washington, the ASILs are supposed to be updated on a three year cycle. Three years would seem to be an adequate frequency for the state standards to keep up with the drift in ACGIH and EPA numbers.

Table 2. Trend in predictive formula over time.								
Date (spring)	Formula	\mathbb{R}^2	#IUR	#IRfC	#Total			
2002	0.000027*TLV ^{1.24}	0.65	32	40	72			
2003	0.000024*TLV ^{1.27}	0.68	31	43	74			
2004	0.000019*TLV ^{1.31}	0.70	31	45	76			

Conclusion

Concerns that the TLV derived ambient air quality standards in Washington and other states are too high or low can be addressed if that concern can be quantified. Regression analysis provides a method. Relative to IRIS values, lower TLV values are less conservative than higher values. Likewise, relative to TLV values, higher IRfC values are less conservative than lower IUR values. Moreover, relative to TLVs, IURs are more conservative than IRfCs. The formula <u>0.000019×TLV^{1.31}</u> can be used to bring ACGIH derived ASILs in line with those derived from IRIS. This exponential formula is superior to the reduction factor approach, while being only slightly more complicated for regulatory agencies to implement.

References

Alavanja M., et al. (1990), Risk assessment for carcinogens: A comparison of approaches of the ACGIH and the EPA, Applied Occupational and Environmental Hygiene 5:510-519.

American Conference of Governmental Industrial Hygienists (2004), <u>2004 TLVs & BEIs</u>, Based on the Documentation of the Threshold Limit Values for Chemical Substances and <u>Physical Agents & Biological Exposure Indices</u>. Herein called "the TLV booklet."

Castleman, B.I., & G.E. Ziem (1988), *Corporate Influence on Threshold Limit Values*, <u>Am. J. of Industrial Medicine</u>, 13:531-559.

Paustenbach, Dennis J. (2000), *Pharmacokinetics and Unusual Work Schedules*, in Harris, Robert L., Ed. (2000), <u>Patty's Industrial Hygiene</u>, <u>Fifth Edition</u>, <u>Vol. 3</u>, Page 1787-1901.

Roach, S.A., & S.M. Rappaport (1990), But They Are Not Thresholds: A Critical Analysis of the Documentation of Threshold Limit Values, Am. J. of Industrial Medicine, 17:727-753.

Whaley, D.V., M.D. Attfield, E.J. Bedillion, K.M. Walter, and Q. Yi (2000), <u>Regression Method to Estimate Provisional TLV/WEEL-equivalents for Non-carcinogens</u>, Am. Occup. Hyg. 44:361-374.

Ziem, G.E., & B.I. Castleman (1989), *Threshold Limit Values: Historical Perspectives and Current Practice*, J. Occ. Med. 31:910-918.

Table 3: 76 substances with both ACGIH TLV & IRIS IUR or IRfC (as of 2004 June 2)											
TLV	TLV	Mol.	IRfC	IUR	ACGIH	IRIS			IRIS		
mg/m3	ppm	Wgt.	mg/m3	mg/m3	class	class	Name	TLV ug/m3	ug/m3		
	40	41.05	0.06		A4	D	Acetonitrile	67157	60		
0.03		71.08		0.0013	A3	B2	Acrylamide	30	0.00077		
	2	72.06	0.001		A4		Acrylic acid	5894	1		
	2	53.05	0.002	0.000068	A3	B1	Acrylonitrile	4339	0.015		
0.25		364.93		0.0049	A3	B2	Aldrin	250	0.0002		
	1	76.50	0.001		A3	C	Allyl chloride	3129	1		
	25	17.03	0.1				Ammonia	17413	100		
8	0	93.12	0.001		A3	B2	Aniline	8000	1		
							Arsenic [elemental & inorganic				
0.01		74.92		0.0043	A1	A	compounds, as As]	10	0.00023		
	0.05	77.95	0.00005				Arsine	159	0.05		

0.1				0.23	A1	A	Asbestos [fibers/m3]	100000	4.35
0.1	0.5	78.11	0.03	0.0000078	A1	A	Benzene	1597	0.13
0.002		9.01	0.02	0.0024	A1	B1	Beryllium [& compounds]	2	0.00042
	0.5	252.80		0.0000011	A3	B2	Bromoform	5170	0.91
	1	94.95	0.005			D	Bromomethane	3883	5
	2	54.09	0.002	0.00003	A2		1,3-Butadiene	4425	0.0036
	20	118.17	13		A3	С	2-Butoxyethanol	96663	13000
0.01		112.40		0.0018	A2	B1	Cadmium	10	0.00056
	10	76.14	0.7				Carbon disulfide	31141	700
	5	153.84		0.000015	A2	B2	Carbon tetrachloride	31460	0.067
0.5		409.80	0.0007	0.0001	A3	B2	Chlordane [technical]	500	0.01
	0.1	67.46	0.0002			D	Chlorine dioxide	276	0.2
	0.05	154.59	0.00003		A4		2-Chloroacetophenone	316	0.03
	1000	86.47	50		A4		Chlorodifluoromethane	3536605	50000
	10	119.38		0.000023	A3	B2	Chloroform	48826	0.043
	300	84.16	6				Cyclohexane	1032638	6000
	10	147.01	0.8		A3		1,4-Dichlorobenzene	60127	800
1		354.50		0.000097	A3	B2	p,p'-Dichlorodiphenyltrichloroethane	1000	0.01
	10	98.96		0.000026	A4	B2	1,2-Dichloroethane	40474	0.038
	5	96.95	0.2	0.00000047	A4	C	1,1-Dichloroethylene	19826	200
	50	84.93	0.004	0.00000047	A3	B2	Dichloromethane	173681	2.13
	75	112.99	0.004	0.000004	A4	D2	1,2-Dichloropropane	346595	0.25
0.0	1	110.98	0.02	0.000004	A4	B2	1,3-Dichloropropene	4539	0.25
0.9		220.98	0.0005	0.0046	A4	B2	Dichlorvos Dieldrin	900	0.5
0.25	10	380.93	0.02	0.0046	A4	B2		250	0.00022
	10	73.09	0.03	0.0000012	A4	D2	N,N-Dimethylformamide	29894 1892	30
	0.5	92.53 90.12	0.001	0.0000012	A3	B2	Epichlorohydrin 2-Ethoxyethanol	18429	0.83 200
	100	64.52	10		4.2				10000
	100	106.16	10		A3	D	Ethyl chloride Ethylbenzene	263885 434192	1000
0.05	100	373.32	1	0.0013	A3	B2	Heptachlor	50	0.00077
0.05		389.40		0.0013	A3	B2	Heptachlor epoxide	50	0.00077
0.002		284.78		0.0026	A3	B2	Hexachlorobenzene	2	0.00038
0.002	0.02	260.76		0.00040	A3	C	Hexachlorobutadiene	213	0.0022
	0.02	272.75	0.0002	0.000022	A4	E	Hexachlorocyclopentadiene	112	0.043
	1	236.74	0.0002	0.0000040	A3	C	Hexachloroethane	9683	0.25
	0.005	168.22	0.00001	0.0000040	113		1,6-Hexamethylene diisocyanate	34	0.23
	50	86.18	0.2				n-Hexane	176237	200
	0.01	32.05		0.0049	A3	B2	Hydrazine [& Hydrazine sulfate]	13	0.0002
	10	34.08	0.002	0,000,0			Hydrogen sulfide	13939	2
							Manganese [elemental and inorganic		
0.2		54.94	0.00005			D	compounds, as Mn]	200	0.05
	5	76.09	0.02				2-Methoxyethanol	15560	20
	50	50.49	0.09		A4	D	Methyl chloride	103252	90
	200	72.10	5				Methyl ethyl ketone	589775	5000
	50	100.16	3				Methyl isobutyl ketone	204826	3000
	50	100.13	0.7		A4	Е	Methyl methacrylate	204765	700
	40	88.17	3		A3		Methyl tert-butyl ether	144245	3000
							Methylene Diphenyl Diisocyanate		
	0.005	250.26	0.0006			D	[monomeric]	51	0.6
	10	128.19	0.003		A4	C	Naphthalene	52429	3
0.1		240.19	_	0.00048	A1	A	Nickel subsulfide [fume and dust, as Ni]	100	0.0021
	10	89.09	0.02		A3		2-Nitropropane	36438	20
	5	94.11	0.3			D	Phenol	19245	300
	0.3	34.00	0.0003			D	Phosphine	417	0.3
		98.00	0.01				Phosphoric acid	1000	10
	100	90.12	2	0.000000	1.5		Propylene glycol monomethyl ether	368589	2000
	2	58.08	0.03	0.0000037	A3	B2	Propylene oxide	4751	0.27
	20	104.16	1	0.000050	A4	- C	Styrene	85202	1000
	1	167.86	0.4	0.000058	A3	C	1,1,2,2-Tetrachloroethane	6865	0.017
	50	92.13	0.4	0.00022	A4	D	Toluene	188405	400
0.5		414.00		0.00032	A3	B2	Toxaphene	500	0.0031
	10	133.41	0.007	0.000016	A4	С	1,1,2-Trichloroethane	54564	0.0625
	1	101.19	0.007		A4		Triethylamine	4139	7
	10	86.09	0.2		A3		Vinyl acetate	35211	200
	0.5	106.96	0.003	0.0000000	A2		Vinyl bromide	2187	3
	100	62.50	0.1	0.0000088	A1	Α	Vinyl chloride	2556	0.11
	100	106.16	0.1		A4		Xylene [m-, o-, p- isomers]	434192	100